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10/517,843	07/12/2005	Greg Swords	37370-339252	9008

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EXAMINER
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GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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12/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/517,843

### Applicant(s)

SWORDS, GREG

### Examiner

Suba Ganesan

### Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/6/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Response to Amendment***

The declaration filed on 9/6/07 under 37 CFR 1.131 has been considered but is ineffective to overcome the cited reference.

For commercial success of a product embodying a claimed invention to have true relevance to the issue of nonobviousness, that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter. Thus a nexus is required between the merits of the claimed invention and the evidence offered, if that evidence is to be given substantial weight in route to a conclusion on the obviousness issue. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881.

In the instant application, a showing of commercial success due to the claimed invention *as opposed to other economic and commercial factors* is lacking.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 11 recites the limitation "said means" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 11 appears to be mistakenly depended from claim 9. Claim 11 has been treated as depending from claim 10 for examination purposes. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim **1, 2, 7, 9-11** are rejected under 35 U.S.C. 102(b) as being anticipated by Wellisz (U.S. Pat. No. 5,743,913).

Wellisz discloses a surgical implant comprising a planar sheet of a thermoplastic resin and a surgical grade metal mesh contained therein (col. 3 lines 43-48), and said implant is able to be bent or displaced by manipulation by hand (col. 2 line 62-col. 3 line 6). With respect to claims 2 and 7, the implant metal is titanium and the thermoplastic resin is polyethylene (col. 3 lines 43-48). With respect to claim 9, the polyethylene comprises a porous surface (col. 3 lines 45-47) that is fully capable of allowing fibrovascular ingrowth. With respect to claims 10-11, the implant has openings that receive and engage the head of a surgical screw or surgical bone anchor (col. 3 lines 7-10).

6. Claims **1-5, 7-8, 10-11, 14-16, 19-21** are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan (U.S. Pat. No. 5,380,328).

7. Morgan discloses a composite surgical implant comprising a planar sheet of thermoplastic resin 42 and a surgical grade metal mesh 46 contained therein,

where the implant is bendable (col. 1 lines 58-60). The metal comprises titanium (see abstract). The top surface and bottom surface comprise smooth barrier surfaces (see fig. 5). The bottom surface further comprises a porous surface (col. 5 lines 41-46) (noting that examiner considers a microporous membrane to be porous). The thermoplastic resin comprises high density polyethylene (col. 4 lines 1-6). The implant further comprises openings for receiving a surgical screw col. 6 lines 42-48). With respect to claims 14-16, Morgan discloses bending a surgical implant having a top and bottom surface comprised of thermoplastic resin and a metallic mesh (see fig. 5) to conform to the profile of a defect in the cranium on a human (col. 2 lines 62-66). With respect to claims 19-21, surgical screws are introduced through the mesh of the implant (col. 6 lines 42-48). The implant can further be cut to conform to the shape of the defect (col. 6 lines 27-30).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wellisz (U.S. Pat. No. 5,743,913) in view of Morgan (U.S. Pat. No. 5,380,328).

10. Wellisz is explained supra, including a surgical implant comprising a planar sheet of a thermoplastic resin and a surgical grade metal mesh contained

therein (col. 3 lines 43-48). However, Wellisz does not disclose a smooth barrier surface. Morgan teaches the use of a barrier (PTFE with a HDPE backing, col. 4 lines 1-6) for the purpose of precluding the passage of unwanted biological cells (see abstract). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wellisz to include a smooth barrier surface on the opposite side of the porous thermoplastic resin (tissue ingrowth region), the motivation to combine being: preventing unwanted cellular infiltration from one side of the implant.

11. Claims **12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable Wellisz (U.S. Pat. No. 5,743,913) in view of Morgan (U.S. Pat. No. 5,380,328), further in view of Cohen et al. (U.S. Pat. No. 6,087,553)

12. Wellisz in view of Morgan is explained supra. In addition, Morgan teaches heat fusing polyethylene barrier surfaces to the implant (see abstract of Morgan). However, Wellisz and Morgan lack the use of a mold with applied heat and pressure. Cohen teaches using heat and pressure to secure polyethylene to an implant surface for the purpose of creating an interface between the polyethylene and the implant surface that is securely fixed and does not allow micro and macro motion between the two materials (see abstract of Cohen). Therefore it would have been obvious to one of ordinary skill in the art to modify the methods of Wellisz and Morgan to include the use of a mold with applied heat and pressure, the motivation to combine being: providing an interface between the polyethylene and the implant surface that is securely fixed and does not allow

micro and macro motion between the two materials. With respect to claim 13, Morgan teaches the use of a barrier on both sides or just one side of an implant if desired (see all figures of Morgan). The examiner considers it to be well within the skill of an ordinary worker in the art, in view of the teachings of Morgan, to provide a thin sheet of PE to be heat fused at either the top or the bottom of the mold for the purpose of securing it to the implant.

13. Claims **17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (U.S. Pat. No. 5,380,328).

14. Morgan is explained supra. However, Morgan lacks specific disclosure of the implant being used in the orbit. It would have been obvious to one of ordinary skill in the art to use the craniofacial implant of Morgan in an orbit, the motivation being: treating an orbital defect. Such a use is well known in the art; it is further known that craniofacial implants can serve as orbital implants. With respect to claim 18, Morgan discloses a top smooth barrier surface and a bottom porous surface (see fig. 5). It would have further been obvious to one of ordinary skill in the art to position the smooth barrier surface towards the orbit, since both sides of the implant comprise both smooth barrier surfaces and porous surfaces and are thus equally suitable to face the orbit.

15. Claim **22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wellisz (U.S. Pat. No. 5,743,913) in view of Scantlebury et al. (U.S. Pat. No. 4,531,916).

16. Wellisz is explained supra, including a surgical implant comprising a planar sheet of a thermoplastic resin and a surgical grade metal mesh contained therein (col. 3 lines 43-48). However, Wellisz is silent as to whether the thermoplastic resin covers the top and bottom surface of the implant. Wellisz is further silent as to the pore size of the polyethylene layer. Scantlebury teaches coating an implant with porous polyethylene with porosity between 50-500 microns (col. 4 lines 52-68) for the purpose of allowing the ingrowth of tissue to secure the implant. Therefore it would have been obvious to one of ordinary skill in the art to modify the implant of wellisz to include a coating of porous polyethylene with a porosity of between 50-500 microns as taught by Scantlebury, the motivation to combine being: providing a coating to allow tissue ingrowth to secure and support the implant.

17. Claim **23** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wellisz (U.S. Pat. No. 5,743,913) in view of Scantlebury et al. (U.S. Pat. No. 4,531,916), further in view of Morgan (U.S. Pat. No. 5,380,328).

18. Wellisz in view of Scantlebury is explained supra. However, the combination lacks a barrier surface of polyethylene. Morgan teaches the use of a barrier (PTFE with a HDPE backing, col. 4 lines 1-6) for the purpose of precluding the passage of unwanted biological cells (see abstract). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wellisz and Scantlebury to include a smooth barrier surface on the opposite side of the porous thermoplastic resin (tissue ingrowth region), the motivation to



combine being: preventing unwanted cellular infiltration from one side of the implant.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 12/6/2007

/William H Matthews/  
Primary Examiner  
AU 3774